REMARKS

Claims 74, 78 and 79 have been amended. The amendment to claim 74 replaces the term "Pgl" with "Phg". Applicants point to paragraph [0138] of the published application for showing that "Phg" is the abbreviation used for "phenylglycine." The amendments to claims 78 and 79 are formalistic in nature. Claims 79-81 have been withdrawn with the understanding that rejoinder is possible upon the determination that the product claim 74 is allowed. No prohibited new matter has been introduced by any of the claim amendments.

1. Objection to the Priority Claim

The Examiner asserts that the claimed priority document (U.S. Provisional Application No. 60/311,404) does not support the currently pending claims because there is allegedly no support in this document for the genus recited in claim 74. Therefore, the Examiner states that the priority date of the claimed subject matter is August 12, 2002 (*i.e.*, the international filing date of PCT/US02/25575).

Based on the Examiner's statements, Applicants presume that the Examiner's search of the prior art in the subject application was conducted without consideration of the priority claims. Applicants have not relied on the filing date of U.S. Provisional Application No. 60/311,404 in this response for arguing patentability of the pending claims over the cited Mazur reference. However, Applicants do not acquiesce to the Examiner's assertion regarding U.S. Provisional Application No. 60/311,404 and reserve the right to contest this assertion at a future date.

2. Rejection under 35 U.S.C. 112, first paragraph

Claim 78 is rejected as allegedly lacking enablement. In support of her rejection, the Examiner cites and addresses the *In re Wands* factors.

Applicants submit that specification as-filed enables the recitation of a pharmaceutical composition comprising the peptidomimetic of claim 74 and a pharmaceutically acceptable carrier. Example 3 discloses a procedure for determining melanocortin receptor specificity for the peptidomimetic compounds of the invention. Examples 11-180 show the results of these determinations for over 170 compounds. Agonist activity levels are assessed for MC1-R, MC3-

R, MC4-R and MC5-R. Example 4 discloses agonist/antagonist status of selected peptidomimetics with respect to MC4-R. Clearly, Applicants have shown an abundance of data regarding the various selectivities of numerous peptidomimetics with respect to melanocortin receptor types and subtypes. Paragraph [0015] of Applicants' published application, for example, describes the association between specific melanocortin receptors and various disorders. While Applicants submit that this statement should be sufficient to enable a claim to a pharmaceutical composition comprising a compound of claim 74, Applicants provide for the Examiner's consideration four review articles that discuss the relationships between the different melanocortin receptor ligands – in particular MC3-R and MC4-R ligands – and the treatment of disorders such as eating disorders, pathological obesity or sexual dysfunction. See *e.g.*, section 3.13 on page 168 of Yang, Emerging Therapeutic Targets; section 6 on page 73 of Wikberg, Expert Opinion on Therapeutic Patents; section 2 on pages 859-860 of Stark, Expert Opinion on Investigational Drugs; and section 2 on pages 1584-1586 and section 4 on pages 1589-1590 of Andersson *et al.*, Expert Opinion on Therapeutic Patents. These provided review articles are representative of the understanding by a person of ordinary skill in the art regarding the potential pharmaceutical uses of the compounds of the invention based on the melanocortin receptor data presented in the examples of Applicants' specification.

Applicants further point the Examiner to Example 17 of commonly assigned Application No. 12/130,299, which shows *in vivo* data for the compound of Example 129 in the subject application (*i.e.*, the elected species in response to the earlier issued Restriction Requirement). In rat model feeding studies, animals dosed with this compound showed a significant decrease in food intake. Applicants submit that these references and data simply confirm the enabling disclosure of the as-filed specification of the subject application. Accordingly, Applicants respectfully request that this rejection be withdrawn.

3. Rejection under 35 U.S.C. 112, second paragraph

Claims 74 and 78 are rejected as allegedly indefinite because the Examiner asserts that the recited terms "Pgl" and "Bpa" are not defined in the specification or claims.

Without acquiescing to the merits of the Examiner's rejection, Applicants have amended claim 74 to replace "Pgl" with "Phg". "Phg" is defined in paragraph [0138] of the published

application as an abbreviation for phenylglycine. Applicants submit that "Bpa" is a well known abbreviation for 4-benzoylphenylalanine and provide the first page of two representative documents as evidence of this submission. Accordingly, Applicants submit that no further amendment to claim 74 is required to overcome this rejection.

4. Rejection under 35 U.S.C. 102(e)

Claims 74 and 78 are rejected as allegedly anticipated by the cited Mazur publication ("Mazur") based on the asserted description in Mazur of MC-3 and MC-4 receptor ligand peptidomimetics and pharmaceutical compositions thereof. The Examiner cites the abstract, pages 4-40 and the SCORE example in Mazur in particular.

Applicants submit that the disclosure of Mazur is extremely broad and there is no specific disclosure of any compounds which would fall within the scope of Applicants' claims. At best, Mazur comprises a *generic* teaching that *any* of a vast number of generically disclosed or specifically named MC-3/MC-4 receptor ligands. More specifically, of all of the categories listed on pages 33-35, 45, 54, 63, 67, 76, 80, 88, 99, 102 and 111, Mazur only discloses how to prepare compounds falling within the categories E, L, "O" (-O-Z instead of Z) and Q and only exemplifies specific compounds falling within these categories. More simply put, the examples of Mazur only disclose how to prepare keto-piperazine compounds. See, *e.g.*, all of the compounds and methods of synthesis on pages 53 to 117. In contrast to the disclosures of Mazur, keto-piperazine compounds are outside the scope of Applicant's claims in the subject application. Trisubstituted piperazines, which are the subject of the claims of the present application, are generically listed in Mazur (see category M on page 34) but there is no disclosure regarding how to prepare compounds of this type. Accordingly, Mazur is not enabling for any compounds which are encompassed by Applicants' claims.

To anticipate a claim, it is not enough that a reference simply makes mention of each component of the claim in lengthy lists of alternatives. Rather, for anticipation the reference must actually describe the claimed invention in sufficient detail to place it in the hands of the skilled person. Thus, for instance, the Federal Circuit stated in *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 58 USPQ2d 1286 (Fed. Cir. 2001):

> Invalidity on the ground of "anticipation" requires lack of novelty of the invention as claimed. The invention must have been known to the art in the detail of the

> claim; that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim. See C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1349, 48 USPQ2d 1225, 1229-30 (Fed. Cir. 1998); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).
> (58 USPQ2d at 1291; emphasis added).

The Federal Circuit stated again in *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research*, 64 USPQ2d 1292 (Fed. Cir. 2002):

> The single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. Crown Operations International, Ltd. v. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002); In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). The anticipating reference "must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996).
> (64 USPQ2d at 1296; emphasis added).

Most generally, it is required that a reference actually describe the particular claimed compound or combination in order to support an anticipation rejection. However, a very narrow generic disclosure in a reference may "describe" the few compounds encompassed therein, but only where the generic formula is *so narrow* that one of ordinary skill in the art is able to "at once envisage" each the specific compound within the generic chemical formula. The classic Federal Circuit decision cited for this narrow exception to the general requirement that a reference, to be an anticipation, must actually name or illustrate the compound is *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962), where a disclosed preferred generic class consisting of only about 20 compounds (including the claimed compound) was found to sufficiently "describe" the compound to anticipate. However, one of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged" and thus anticipated by the reference. MPEP 2131.02.

Applying *Petering* to the present circumstance, there are thousands of compounds encompassed by the disclosure of Mazur, far outside of the 20 compounds within the very limited genus of *In re Petering*.

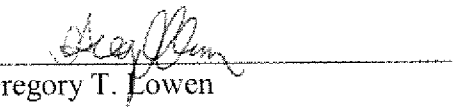
It is therefore respectfully submitted that the generic disclosure of MC-3/MC-4 receptor ligands in Mazur does not even come close to meeting the very narrow genus criteria set out in *In re Petering*, and clearly is not sufficiently descriptive of the presently claimed combination to constitute an anticipation thereof. It is therefore requested that this rejection be withdrawn.

5. Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments and the timely allowance of the pending claims. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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